presentation on early warning from representatives of the Advisory Council on Governmental Audit Standards.

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

FOR FURTHER INFORMATION CONTACT: Wendy Comes, Executive Director, 441 G St., NW., Room 3B18, Washington, DC 20548, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: July 16, 1998.

Wendy M. Comes,

Executive Director.

[FR Doc. 98–19417 Filed 7–20–98; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Public Law 92–463) of October 6, 1972, that the Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy Sites of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services, has been renewed for a 2-year period beginning July 7, 1998 through July 7, 2000.

For further information, contact the Management Analysis and Services Office, Committee Management and Program Panels Activity, CDC, Mailstop E–72, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404–639–6389 or fax 404–639–6290.

Dated: July 13, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–19326 Filed 7–20–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0515]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by August 20, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles—(21 CFR Part 226)—(OMB Control Number 0910–0154—Reinstatement)

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (CGMP) regulations for drugs, including Type A medicated articles. A Type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for CGMP's for Type A medicated articles have been codified under part 226 (21 CFR part 226). Type A medicated articles that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under part 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under the manufacturing process to ensure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing), and product distribution. This information is needed so that FDA can monitor drug usage and possible misformulation of Type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the CGMP criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to ensure that their medicated articles meet the requirements of the act pertaining to safety and also meet the articles, claimed identity, strength, quality and purity, as required by section 501(a)(2)(B) of the act.

The respondents for Type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs and commercial feed mills.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.42	200	120	24,000	0.75	18,000
226.58	200	120	24,000	1.75	42,000
226.80	200	120	24,000	0.75	18,000
226.102	200	120	24,000	1.75	42,000